UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA

Alexandria Division

UNITED STATES OF AMERICA

v.

DAVID E. BURKE,
a/k/a "David Johnson,"

Defendant

Criminal No. 1:14-cr-397-3

Hon. Anthony J. Trenga

STATEMENT OF FACTS

The United States and the defendant, DAVID E. BURKE, agree that the following facts are true and correct, and that had this matter proceeded to trial, the United States would have proven them beyond a reasonable doubt with admissible and credible evidence:

1. Beginning in at least April 2011, and continuing until December 2014, in the Eastern District of Virginia and elsewhere, defendant DAVID E. BURKE, a/k/a "David Johnson," together with co-conspirators including TC MEDICAL GROUP, SB MEDICAL INC., TZVI LEXIER, HANOCH DAVID STEIN, a/k/a "Albert Simmins," ASAF AKIVA IBRAHIMIAN, a/k/a "Adam Darius," and REUVEN MIRLIS, a/k/a "Daniel Mirl," and other individuals including co-conspirators based in Canada, including R.L. and S.R., co-conspirators in Germany, including C.G., and co-conspirators in the United States, including A.T. in Baltimore, Maryland; R.R. and M.R. in Lakewood, New Jersey; S.M. and E.M. in Edison, New Jersey; and A.B. in Boynton Beach, Florida, and with intent to defraud and mislead, engaged in a conspiracy to smuggle into and distribute within the United States, including within the Eastern District of Virginia, misbranded prescription drugs and devices.

2. The misbranded and non-FDA approved prescription drugs and devices smuggled and sold in the United States by the conspiracy included the following:

Product	Use
Aclasta	Injectable drug used to treat osteoporosis (bone decay). Not FDA-approved for use in the United States. Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F).
Actemra	Injectable prescription drug used to treat rheumatoid arthritis (joint inflammation). Subject to FDA black-box warning: "[I]ncreased risk for developing serious infections that may lead to hospitalization or death." Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F), and away from light and moisture.
Artzal	Injectable device used to treat osteoarthritis (joint pain). Not FDA-approved for use in the United States.
Bonviva	Injectable infusion drug used to treat of osteoporosis (bone decay). Not FDA-approved for use in the United States.
Botox	Injectable prescription drug used to treat bladder disorders, chronic migraines, muscle spasms, and abnormal head positions. Subject to FDA black-box warning: "Swallowing and breathing difficulties can be life threatening and there have been reports of death." Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F).
Botox Cosmetic	Injectable prescription drug used to treat forehead wrinkles. Subject to FDA black-box warning: "Swallowing and breathing difficulties can be life threatening and there have been reports of death." Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F).
Dysport	Injectable prescription drug used to treat abnormal head positions and forehead wrinkles. Subject to FDA black-box warning: "Swallowing and breathing difficulties can be life threatening and there have been reports of death." Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F), and away from light.
Euflexxa	Injectable Class III prescription device used to treat osteoarthritis (joint pain). Must be kept away from light.
Hyalgan	Injectable Class III prescription device used to treat osteoarthritis (joint pain).
Juvederm	Injectable Class III prescription device used to treat facial wrinkles and folds. Juvederm 2, Juvederm 3, and Juvederm 4 are not FDA-approved for use in the United States.
Lucentis	Injectable prescription drug used to treat macular degeneration of the eye. Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F), and away from light.
Mabthera	Injectable prescription chemotherapy drug not FDA-aproved for use in the United States. Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F), and away from direct sunlight or shaking.

Macrolane	Injectable Class III device used for body contouring. Not FDA-approved for use in the United States.
Orencia	Injectable prescription drug used to treat rheumatoid arthritis (joint inflammation). Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F), and away from light and freezing.
Orthovisc	Injectable Class III prescription device used to treat osteoarthritis (joint pain).
Prolia	Injectable prescription drug used to treat osteoporosis (bone decay). Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F), and away from light, heat, and vigorous shaking.
Radiesse	Injectable Class III prescription device used to treat facial wrinkles and folds.
Remicade	Injectable prescription drug used to treat rheumatoid arthritis (joint inflammation), bowel inflammation, skeletal inflammation, skin inflammation, and other conditions. Subject to FDA black-box warning: "Increased risk of serious infections leading to hospitalization or death, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis) and infections due to other opportunistic pathogens." Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F).
Restylane	Injectable Class III prescription device used to treat facial wrinkles and folds, lip-filler.
Supartz	Injectable Class III prescription device used to treat osteoarthritis (joint pain).
Synvisc	Injectable Class III prescription device used to treat osteoarthritis (joint pain).

3. Specifically, members of the conspiracy did knowingly and intentionally combine, conspire, confederate, and agree, with each other and with other persons, to: (a) defraud the United States and its agencies by: impeding, impairing, and defeating the lawful functions of the Food and Drug Administration ("FDA") to protect the health and safety of the public by ensuring that prescription drugs and devices distributed in the United States were safe and effective from the time of manufacturing to the delivery to the entity that sold or dispensed the product to the ultimate consumer or patient; and impeding, impairing, and defeating the lawful functions of Customs and Border Protection ("CBP") and Immigration and Customs Enforcement—Homeland Security Investigations ("ICE-HSI") to protect the public health and

safety by governing the importation into the United States of goods and merchandise, including drugs and devices, through deceitful and dishonest means; (b) fraudulently and knowingly import and bring into the United States merchandise contrary to law, and receive, conceal, buy, sell, or in any manner facilitate the transportation, concealment, or sale of such merchandise after importation, knowing the same to have been imported or brought into the United States contrary to law; (c) introduce into interstate commerce misbranded prescription drugs and devices; and (d) knowingly engage in the wholesale distribution in interstate commerce of prescription drugs in the United States, including to the Commonwealth of Virginia without being licensed to do so.

4. The misbranded and non-FDA approved prescription drugs and devices smuggled and sold by members of the conspiracy included orthopedic injections, rheumatology infusions, cosmetic devices, optomology products, and oncology drugs, which were often subject to stringent storage and handling requirements (such as cold-chain products required to be kept at a consistently low temperature for their safe use), and FDA "black box warnings" which is the strongest warning the FDA requires. The FDA requires "black box warnings" when a drug carries a significant risk of serious or life-threatening adverse effects.

5. The prescription drugs and devices smuggled and distributed by members of the conspiracy were misbranded because they failed to bear adequate directions for use in that they, among other things, (a) were not in the possession of a person, or his agents or employees, who was regularly and lawfully engaged in the storage or wholesale distribution of prescription drugs or devices; (b) failed to bear a label that contained the required language limiting their use to prescription only and for prescription drugs; (c) failed to bear the FDA-approved labeling and/or at any time before dispensing its label failed to bear, at a minimum, the "Rx only" symbol. The

drugs and devices were also misbranded in some cases because the required labeling failed to bear information required under the FDCA in the English language. 21 U.S.C. § 352(f)(1).

6. In addition, neither defendant DAVID E. BURKE nor any of his co-defendants and co-conspirators were licensed wholesale distributors permitted to sell prescription drugs within the United States and in the Commonwealth of Virginia, and so were not regularly and lawfully engaged in the storage or wholesale distribution of prescription drugs or devices in the United States. Neither BURKE nor any of his co-defendants and co-conspirators adhered to appropriate storage and handling, record-keeping, and reporting requirements as would be required of lawful and licensed wholesalers in the United States. In particular:

a. Facilities used by members of the conspiracy for the storage and handling of prescription drugs and devices consisted of unregistered commercial mailboxes at United Parcel Service ("UPS") and other commercial vendors, residential backyards and porches, basement rooms, garages, kitchen fridges and freezers, and personal residences which did not have adequate lighting, ventilation, temperature, humidity, and security as required for the safe handling and storage of prescription drugs and devices. Members of the conspiracy—who did not have any formal training or experience in handling prescription drugs and devices—did not properly quarantine damaged, deteriorated, misbranded, or adulterated prescription drugs and in some cases caused them to be shipped to United States doctors and medical practices.

b. Shipping methods used by members of the conspiracy were designed to evade law enforcement detection, and so often took weeks to arrive in the United States from abroad. Instead of using dry ice or other means of appropriately packing prescription drugs and devices and shipping them by overnight mail, members of the conspiracy often used ice packs and cooling packs, Styrofoam boxes, and other picnic cold packs from Walmart or other stores

for shipment over longer periods of time, and often failed to keep cold chain prescription drugs at the required temperatures altogether. As a result, certain FDA-regulated products required to be kept at low and specific temperatures routinely arrived warm, wet, or otherwise damaged.

c. Members of the conspiracy, not being regularly and lawfully engaged in the storage or wholesale distribution of prescription drugs or devices in the United States, did not keep the required records and reports as required of lawful and licensed wholesalers in the United States.

7. Defendant DAVID E. BURKE agrees that TC MEDICAL GROUP and SB MEDICAL INC., under the leadership and supervision of TZVI LEXIER and C.G., caused misbranded and non-FDA approved prescription drugs and devices to be smuggled into the United States and distributed as follows:

a. Beginning in or around April 2011, members of the conspiracy purchased from co-conspiring foreign suppliers prescription drugs and devices manufactured and labeled for use in foreign countries, including the Republic of Turkey, Canada, France, Italy, the United Kingdom, and other countries, and caused them to be shipped into the United States. These prescription drugs and devices were forwarded to the United States through the United Kingdom to doctors and medical practices in the United States, or alternatively to locations including the personal residences and mailboxes of co-conspiring individual drop shippers in the United States.

b. Drop shippers in the United States regularly received packages of prescription drugs and devices from abroad, removed labels and other indicia showing that they had been imported from abroad, repacked the orders, and re-shipped them to doctors and medical

practices throughout the United States, including to the Eastern District of Virginia, to give the false impression that the drugs were being distributed domestically and legally.

c. To impede, impair, and defeat the lawful functions of the FDA, CBP, and ICE-HSI, the defendants, together with other co-conspirators, engaged in deceitful and dishonest means, including: (i) breaking up large shipments of prescription drugs and devices into smaller separate packages to be sent into the United States to multiple locations, under multiple names, over multiple days, to be consolidated upon arrival after evading border detection; (ii) shipping packages via Royal Mail and Parcelforce Worldwide, which—because they were United Kingdom-based services—allowed packages to be delivered through the United States Postal Service with less scrutiny than would be applied to packages arriving from other countries; (iii) including on customs forms misleading statements about the package contents and value, and addressing packages to co-conspirators under false names and/or titles; (iv) frequently mishandling prescription drugs subject to strict temperature requirements by failing to keep them at a consistent temperature during shipping and storage as required for the drug's safe and effective use; and (v) failing to keep and provide the appropriate pedigree records to prove or track the proper shipping, storage, and transaction history of prescription drugs through the supply chain.

8. Defendant DAVID E. BURKE's role was to participate in the day-to-day operations of TC MEDICAL GROUP and SB MEDICAL INC. Among other things, and working with co-defendant TZVI LEXIER and others, BURKE communicated with co-conspirator sales representatives and drop shippers in the United States, tracked and coordinated shipments from overseas into the United States, called United States-based customers to sell prescription drugs and devices from abroad, and engaged in the illegal importation and sales of

misbranded drugs and devices. BURKE used the false name "David Johnson" in connection with his activities.

9. Between approximately April 2011 and approximately December 3, 2014, defendant DAVID E. BURKE, received approximately $1,292,650.77 in United States dollars and approximately $8,974.95 in Canadian dollars as payments for the sale of misbranded and non-FDA approved drugs and devices in the United States, including into the Eastern District of Virginia, for the TC MEDICAL GROUP and SB MEDICAL INC. organization. From approximately April 2011 through December 3, 2014, TC MEDICAL GROUP and SB MEDICAL INC. caused to be illegally imported and distributed misbranded prescription drugs and devices within the United States and the Eastern District of Virginia, misbranded and non-FDA approved prescription drugs and devices amounting to approximately $18,494,285 in gross proceeds.

10. For example, on or about the following dates, defendant DAVID E. BURKE, together with others, caused the following misbranded prescription drugs and devices to be smuggled into the United States and introduced into interstate commerce in the Eastern District of Virginia:

2/27/14	DAVID E. BURKE	2 boxes of Botox, 1 box of Juvederm to Leesburg, Virginia
3/12/14	DAVID E. BURKE	2 boxes of Botox, 1 box of Juvederm, 1 box of Restylane to Leesburg, Virginia
4/2/14	DAVID E. BURKE	3 boxes of Botox to Leesburg, Virginia
4/25/14	DAVID E. BURKE	2 boxes of Botox, 1 box of Juvederm to Leesburg, Virginia
7/11/14	DAVID E. BURKE	3 boxes of Botox to Leesburg, Virginia

11. In addition, members of the conspiracy regularly communicated with each other via email about the foreign acquisition, illegal importation, sale of misbranded prescription drugs and devices in the United States, and the transfer of proceeds from the United States back to Canada. For example:

a. On May 31, 2011, co-defendant HANOCH DAVID STEIN informed co-defendant TZVI LEXIER and defendant DAVID E. BURKE: "customers have been complaining about the Botox arriving warm. Storing and purchasing dry ice is complicated, also it freezes the good... Up until now I have been using smaller coolers (with a thinner wall) and smaller ice packs (to save on shipping)."

b. On September 15, 2011, defendant DAVID E. BURKE instructed co-defendant HANOCH DAVID STEIN to "ship 6 turkish 8 juvederm" to a doctor in Utah.

c. On December 12, 2011, co-defendant HANOCH DAVID STEIN informed co-defendant TZVI LEXIER that: "3 Turkish from [a doctor] FYI They were sent in an envelope (warm) They are taped together. Let me know if you can sell them and who I should send them to." A co-conspirator responded: "david, please put them in the fridge - we are selling them as normal."

d. On December 14, 2011, defendant DAVID E. BURKE and a co-conspirator discussed misbranded prescription drugs being imported into the United States under the false name of "Albert Simmins."

Co-conspirator :	botox was shipped to your dad, stein, albert simmins turkey will also shipped today
BURKE:	albert simmins?
Co-conspirator:	steins new name :)
BURKE:	jesus i hope that doesnt present a problem
Co-conspirator:	no he told us a new address
BURKE:	does he have ID for that name to pick up packages
Co-conspirator:	and we can use that name don't know but tzvi also confirmed that name

BURKE: ok

e. On February 21, 2012, defendant DAVID E. BURKE and a co-conspirator discussed the illegal importation of prescription drugs and devices into the United States:

BURKE:	...please keep what your doing on the down low if possible...
Co-conspirator:	...pharmaceuticals have very very specific laws. be extremely careful with that. I'd check the with the FDA and DOJ sites...
BURKE:	importing "medical devices" for sale is against the law as well... the more iv researched the more i realize that it aint so kosher ... there are companies and docotrs losing there licences over "importing" all the time... you shoudl make as much as you can while you can... i go with the thought of every day is my last and make the best of it.

f. On April 10, 2012, defendant DAVID E. BURKE falsely represented to a medical practice in McLean, Virginia, in the Eastern District of Virginia that: "Frozen products such as Botox are shipped only by overnight Priority FedEx (medical/frozen special handling) on several kilograms of dry ice... All products are transported and stored in climate controlled environments. Frozen products such, as Botox, are maintained in a cold storage facility at all times and our partner pharmacies are fully licensed t o dispense & ship medication."

g. On September 10, 2012, defendant DAVID E. BURKE, in an email copying co-defendant TZVI LEXIER, instructed a drop shipper in the United States that: "The procedure should be as follows: 1. Box comes to you. 2. You open and count the products in each box. 3. You then send an email to accounting@tcmedicalgroup.com and report how many boxes came in and what was in each box. (Example: hello, I received 5 boxes today, box 1 was 20 synvisc, box 2 was 30 euflexxa, box3 was 10 orthovisc etc etc...) 4. You then pack all the stuff into one box and make sure to use packing tape, as well please handle these products with care and then head over to the local shop and ship them to Baltimore."

h. On December 4, 2012, defendant DAVID E. BURKE forwarded to co-defendant TZVI LEXIER a letter from the FDA which had warned doctors that:

> Purchasing Unapproved Medications from Foreign or Unlicensed Suppliers Could Result in Serious Harm to Patients... Most, if not all, of the products sold and distributed by these [foreign] suppliers, including versions of Botox, have not been approved by FDA. The manufacture and handling of these products may not be of suitable quality to ensure safety or efficacy, and the products have not been proven to be safe and effective pursuant to FDA standards. FDA is very concerned that products distributed by these suppliers may cause harm to patients, because they may be unsafe or ineffective. Medications obtained from... foreign or unlicensed suppliers may be from unknown sources, may have unknown ingredients, may be counterfeit, or may not have been manufactured, transported or stored under proper conditions as required by US law, regulations, and standards. Such products put patients at risk of exposure to ineffective or dangerous products. In virtually all cases, importing or causing the importation of unapproved prescription medications from foreign sources violates the Federal Food, Drug, and Cosmetic Act and is illegal.

i. On January 15, 2013, co-defendant TZVI LEXIER forwarded to a co-conspirator an email from defendant DAVID E. BURKE with the headline: "FDA takes action against illegal drug importation of Botox" which noted: "Importation without FDA approval is illegal. According to the United States Federal Food, Drug, and Cosmetic Act (FDCA), unauthorized drugs that are imported are considered unapproved, misbranded, and adulterated (21 U.S.C. 331)."

j. On May 28, 2013, a drop shipper in the United States wrote to defendant DAVID E. BURKE: "Don't know if this is a problem but one of the boxes of orencia was wet when I took it out of cooler today." A co-conspirator responded: "please Refrigerate the damaged box of Orencia, but put it separately from the other Orencia. We have one client or two that doesn't mind taking damaged boxes. When we receive an order from them we will send the damaged Orencia...."

k. On July 24, 2013, defendant DAVID E. BURKE emailed: "did the botox arrive, or are we goign to flood us customs with 200 botox again."

l. On or about July 28, 2013, defendant DAVID E. BURKE emailed co-conspirators, including co-defendant TZVI LEXIER, that: "I do not want us sending lots of Botox into the us at one time."

m. On August 14, 2013, defendant DAVID E. BURKE emailed a co-conspirator noting: "invoices are mislabeled in order to get it into the country. You stand to lose a lot here if the s--- hits the fan." BURKE then emailed co-defendant TZVI LEXIER and a co-conspirator that: "I want to start royal mailing all fillers going forward... Turkish Botox going forward is probably not the best option to be utilizing... Dysport... we only need maximum 100 a month....this can be broken down to small shipments of 20 over a 4 week period... I also recommended to all guys here to stay low for now... tzvi agrees with this."

n. On September 16, 2013, a co-conspirator forwarded to defendant DAVID E. BURKE a letter stating that: "In nearly all instances, drugs and devices purchased from pharmacies are not approved for use within the United States... Given the lack of control over the standards governing the manufacture and distribution of foreign-sourced drugs and devices, it is not difficult to understand the interest federal regulators have in enforcing the prohibitions concerning the importation of such drugs and devices.... The FDCA provides for criminal liability for bringing an adulterated or misbranded drug into interstate commerce..."

o. On December 4, 2013, a drop shipper in the United States emailed to defendant DAVID E. BURKE an FDA letter stating that a shipment had been detained. BURKE responded: "Its OK.... don't worry happens all the time."

p. On January 3, 2014, defendant DAVID E. BURKE emailed co-defendant TZVI LEXIER and another co-conspirator an email with subject line "Oncology products" and noted: "Please let me know what products we can get our hands on... English Packaging will be an easier and safer sale."

q. On January 7, 2014, a drop shipper in the United States emailed defendant DAVID E. BURKE: "shipped radiesse today to baltimore, also, got another letter from the FDA," BURKE responded: "Regarding orthopedic again ?"

r. On January 15, 2014, a drop shipper in the United States emailed defendant DAVID E. BURKE that "[t]his came to our house" and enclosed a letter from the FDA stating that a shipment of product had been detained. BURKE noted: "It really isn't a big issue at all. Still decreasing isn't a bad idea."

s. On December 16, 2014, defendant DAVID E. BURKE texted co-defendant TZVI LEXIER that:

> My point is the way you talk about the guy who helped build your business the MOST instrumental part of this company from day f--king one... I have given my blood, sweat and tears for this company from day f--king one. I'm the best thing that ever happened to you... No one will ever be able to do what I did for you. It isn't just the cosmetics... it's the infrastructure I'm which we rely on daily to this day. The FDA agents that have had there attention drawn elsewhere... the clients that would have left in all departments had I not got involved you and chris just saw the money... not what it took to make sure it stayed in all our pockets. You underestimate me Tzvi.

12. In addition, from at least October 2011 through at least October 2014, in the Eastern District of Virginia and elsewhere, defendant DAVID E. BURKE, together with co-defendants TC MEDICAL GROUP, SB MEDICAL INC., TZVI LEXIER, HANOCH DAVID STEIN, a/k/a "Albert Simmins," ASAF AKIVA IBRAHIMIAN, a/k/a "Adam Darius," and REUVEN MIRLIS, a/k/a "Daniel Mirl," and others, did knowingly combine, conspire, and agree with each other and with others to commit offenses against the United States in violation of Title 18, United States Code, Section 1956, to wit: to transport, transmit and transfer and attempt to transport, transmit and transfer a monetary instrument and funds from a place in the United States to and through a place outside the United States with the intent to promote the carrying on

of specified unlawful activity, to wit: fraudulently and knowingly import and bring into the United States merchandise contrary to law, and receive, conceal, buy, sell, or in any manner facilitate the transportation, concealment, or sale of such merchandise after importation, knowing the same to have been imported or brought into the United States contrary to law, in violation of Title 18, United States Code, Section 545, in violation of Title 18, United States Code, Section 1956(a)(2)(A).

13. Specifically, defendant DAVID E. BURKE, together with his co-conspirators, moved the proceeds from the sale of misbranded prescription drugs and devices which had been imported contrary to law from the United States to bank accounts in Canada in two main ways. First, the defendants used credit card payment systems and processors to transfer proceeds from the United States to Canada. Second, co-conspirator drop shippers based in the United States received payment checks by mail, bundled them, and forwarded them to Canada to be deposited into bank accounts, all to give the false impression to customers including doctors and medical practices that the defendants operated legally in the United States. In this manner, the conspiracy caused at least $14,786,900 to be transferred from payment card transactions, including VISA and MasterCard into the bank account of defendant SB MEDICAL INC. in Canada. Payment card transactions of VISA were conducted through servers in Ashburn, Virginia, in the Eastern District of Virginia.

14. Once the funds were in the bank account of co-defendant SB MEDICAL INC., the conspirators caused further financial transactions to be made in furtherance of the conspiracy, including:

a. Payments amounting to millions of dollars to foreign co-conspirator suppliers to obtain supplies of prescription drugs and devices intended for the illegal importation into the United States;

b. Payments amounting to millions of dollars to co-conspirator salespersons in the United States and Canada, including co-defendants ASAF AKIVA IBRAHIMIAN, REUVEN MIRLIS, and defendant DAVID E. BURKE, representing commission payments for the illegal importation and sale of misbranded prescription drugs and devices within the United States on behalf of TC MEDICAL GROUP and SB MEDICAL INC.

c. Payments amounting to hundreds of thousands of dollars to co-conspirator drop shippers in the United States, including co-defendant HANOCH DAVID STEIN, representing payments for receiving, repacking, and resending misbranded prescription drugs and devices to other customers or locations within the United States.

d. Distributions amounting to hundreds of thousands of dollars to co-conspirator and principal of TC MEDICAL GROUP and SB MEDICAL INC., co-defendant TZVI LEXIER.

15. On December 23, 2014, after being advised of his *Miranda* warnings, defendant DAVID E. BURKE voluntarily admitted, among other things, the following to law enforcement officers: that he had been involved in the smuggling and selling conspiracy by the TC MEDICAL GROUP and SB MEDICAL INC. BURKE; that he worked for defendant TC MEDICAL GROUP in Canada, along with other co-conspirators in Canada, Germany, and the United Kingdom; that three years ago, he spoke with co-defendant Tzvi Lexier and his father, R.L., about joining; that non-FDA drugs were being shipped from the United Kingdom to various locations in the United States (Baltimore, MD and New Jersey) and sold to doctors and

clinics; that cold-chain products were not kept cold as required; that to his knowledge there was no valid license to sell prescription drugs and devices in the United States; that in dealing with United States customers he "for sure lied to people plenty" and when asked if they could get in trouble, would "shirk" the answer; that large shipments of pharmaceuticals would be broken up into smaller portions to avoid detection at the border; that he used aliases and multiple email accounts to sell misbranded pharmaceuticals to the United States; that—despite receiving notice of FDA-letters detaining drugs—he kept selling; that he was aware that packages arriving from abroad would have labels remove (to hide their foreign origin); that he knew the conduct was illegal and "I should have gotten out of it, definitely."

16. The statement of facts includes those facts necessary to support the defendant's guilty plea. It does not include each and every fact known to the defendant or to the government and it is not intended to be a full enumeration of all of the facts surrounding the defendant's case.

17. The actions of the defendant, as recounted above, were in all respects knowing, voluntary, and intentional, and were not committed by mistake, accident or other innocent reason.

18. The defendant waives any rights under Fed. R. Crim. P. 11(f), Fed. R. Evid. 410, the United States Constitution, and any federal statute or rule in objecting to the admissibility of the Statement of Facts in any such proceeding.

Dana J. Boente
United States Attorney

By: _____
Alexander T.H. Nguyen
Kellen S. Dwyer
Jay V. Prabhu
Assistant United States Attorneys

Defendant's Signature: After consulting with my attorney, I hereby stipulate that the above Statement of Facts is true and accurate and that had the matter proceeded to trial, the United States would have proved the same beyond a reasonable doubt.

Date: 3/9/15, 2015

David E. Burke
Defendant

Defense Counsel Signature: I am David E. Burke's attorney. I have carefully reviewed the above Statement of Facts with him. To my knowledge, his decision to stipulate to these facts is an informed and voluntary one.

Date: 3/9/15, 2015

Stuart A. Sears, Esq.
Marc Agnifilo, Esq.
Counsel for the Defendant